EXHIBIT 3

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REVIEW ARTICLE

Retropubic or transobturator mid-urethral slings for intrinsic sphincter deficiency-related stress urinary incontinence in women: a systematic review and meta-analysis

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Abstract
Introduction and hypothesis Stress urinary incontinence is a common problem affecting 12-46 % of women. A cohort of women have a more severe form of stress urinary incontinence usually due to intrinsic urethral sphincter deficiency that has traditionally resulted in lower success rates with standard treatment modalities. We aim to address the question of whether transobturator sling insertion is more effective than retropubic sling insertion in the treatment of intrinsic sphincter deficiency-related stress urinary incontinence in women.
Methods We searched MEDLINE, CINAHL, CENTRAL, journals, and major conferences (up to 30 June 2014). All randomised controlled trials in women with stress urinary incontinence or mixed urinary incontinence with associated intrinsic sphincter deficiency who underwent a retropubic or transobturator mid-urethral sling operation were included in this meta-analysis. The Cochrane risk of bias tool and the GRADE system were used to assess the quality of evidence.
Results Fifty-five randomised controlled trials compared transobturator and retropubic mid-urethral slings. Twelve trials included women with intrinsic sphincter deficiency, but only 8 trials (399 women) reported data specifically for this cohort. There was a statistically significant difference in short- and medium-term (≤5 years) subjective cure rates, with the number of women reporting a cure in the transobturator group at 150 out of 199 and the retropubic group at 171 out of 200. This gives a 12 % relative risk reduction in achieving cure with the transobturator route (RR 0.88, 95 % CI 0.80 to 0.96, $I^2=0$ %, moderate quality evidence [GRADE]). Objective cure was reported by five trials of 324 women and showed no statistically significant difference between the two groups, with a rate of 110 out of 159 in the transobturator group and 126 out of 165 in the retropubic group (RR 0.90, 95 % CI 0.79 to 1.03). Post-operative voiding dysfunction and de novo urgency or urgency urinary incontinence in the two treatment groups showed no significant difference. The need to undergo repeat incontinence surgery in the long term (≥5 years) was higher with the transobturator route (RR 14.4, 95 % CI 1.95 to 106, 147 women).
Conclusions Mid-urethral slings are effective in treating women with intrinsic sphincter deficiency-associated stress urinary incontinence. The retropubic route resulted in higher subjective cure rates compared with transobturator routes. Both routes improved the overall quality of life.

Keywords Stress urinary incontinence · Intrinsic sphincter deficiency · Mid-urethral slings · Transobturator · Retropubic · Systematic review · Meta-analysis

Abbreviations

CENTRAL	The Cochrane Central Register of Controlled Trials
ISD	Intrinsic sphincter deficiency
MUCP	Maximum urethral closure pressure
MUI	Mixed urinary incontinence
MUS	Mid-urethral sling
QoL	Quality of life
RCT	Randomised controlled trial
RPR	Retropubic route

This abstract has been accepted to the International Urogynaecology Association (IUGA) meeting in Nice 2015 for oral podium presentation

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SUI	Stress urinary incontinence
TOR	Transobturator route
VLPP	Valsalva leak point pressure

Introduction

Stress urinary incontinence (SUI), which is the involuntary loss of urine on effort or physical exertion or on sneezing or coughing, is associated with significant physical morbidity, sexual dysfunction, loss of independence and a reduction in psychological well-being. In women the prevalence is between 12 and 46 % [1].

Stress urinary incontinence was classified by Green [2] into two types: type I is caused by the loss of the posterior urethrovesical angle, and type II is the loss of the posterior urethrovesical angle in association with urethral hypermobility. This hypermobility is the downward displacement of the urethra with a maximal straining angle of ≥30° from baseline [3].

A more severe form of SUI was identified by McGuire [4, 5] and classified as type III. This is where leakage of urine is associated with very low urethral closure pressures. This can be in the presence or absence of hypermobility. This is termed intrinsic sphincter deficiency (ISD). Standardisation of a definition of ISD has been difficult, but is widely accepted to be maximal urethral closure pressure (MUCP)<20 cm H_2O or Valsalva leak-point pressure (VLPP) of <60 cm H_2O. This diagnosis poses a great challenge to treatment, with much lower rates of surgical success [4].

Historically, autologous fascial pubovaginal slings were used as the standard treatment for ISD. With the advent of minimally invasive procedures, currently the most favoured treatment for both SUI and ISD-associated SUI is the mid-urethral sling (MUS). The commonest types of MUS used are those traversing the transobturator route (TOR) or the retropubic route (RPR). With evidence from collated randomised controlled trials (RCT) we aim to ascertain the best approach to MUS insertion, providing the most efficacious treatment for ISD-associated SUI.

Materials and methods

This systematic review of controlled clinical trials was conducted in accordance with the systematic review guidelines provided by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist. No institutional board review approval was necessary.

Strategy for literature review and study selection

We searched the Cochrane Incontinence Group Specialised Register, which contains trials identified from CENTRAL, MEDLINE, MEDLINE in process, ClinicalTrials.gov and we hand-searched journals and conference proceedings (searched on 30 June 2014), Embase and Embase Classic (January 1947 to Week 25 2014), WHO ICTRP (searched on 30 June 2014) and the reference lists of relevant articles. The search strategy is demonstrated in Appendix 1. There were no language restrictions.

Criteria for considering studies for this review were formed in Participants, Interventions, Comparisons and Outcomes (PICO) format. Two reviewers independently examined the titles and abstracts of all studies identified using the search strategy to determine eligibility for inclusion. After exclusion of studies by assessing titles and abstracts, and removal of the duplicates, a full text review was performed and a study selection form was completed to document the reason for inclusion/exclusion. Where necessary, trial authors were contacted. Randomised or quasi-randomised trials in women with ISD-associated SUI or mixed urinary incontinence (MUI) were included.

Data extraction and outcomes

Two of the review authors extracted data independently. Information extracted from eligible trials included: authors' names, journal, year of publication, length of follow-up, number of participants, patient demographics and trial outcomes. Our primary outcome was subjective cure, as defined by trialists as patient self-reported absence or improvement in SUI symptoms. Secondary outcomes included objective cure, intra-operative and post-operative adverse events, need for repeat incontinence procedures, quality of life and economic measures.

Methodological quality assessment and statistical analysis

Risk of bias for the studies included was assessed using the Cochrane risk of bias tool. Seven evidence-based domains

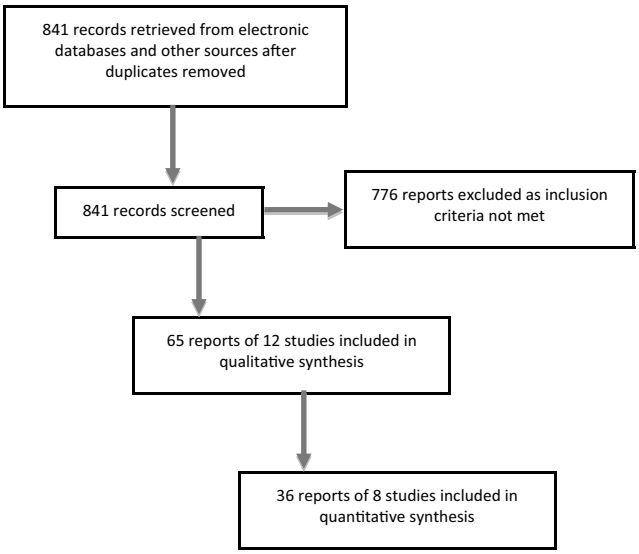

Fig. 1 Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow chart

Table 1 Characteristics of the studies included

Study	Population size (number of women)	MUS used	ISD definition	Outcome measures	Mean follow-up (months)	Cure
Deffieux et al. [10]	18	TVT-O	MUCP≤30 cm H_20	Objective cure (stress test) Subjective cure (absence of SUI symptoms)	24	Subjective: TVT-O (60 %); TVT (62.5 %)
		TVT		CONTILIFE (QoL)		Objective: N/A
Karateke et al. [16]	36	TVT-O	VLPP≤60 cm H_20	Subjective cure (absence of SUI symptoms)	14	Subjective: TVT-O (88.9 %); TVT (88.9 %)
		TVT		IIQ-7, UDI-6		Objective: N/A
Kim et al. [19]	9	TOT (Monarc)	VLPP≤60 cm H_20	Subjective cure (absence of SUI symptoms)	32	Subjective: TOT (100 %); TVT (50 %)
		TVT				Objective: TOT (100 %); TVT (50 %)
Oliveira et al. [17]	42	TVT-O	VLPP≤60 cm H_20	Objective cure (stress test)	12	Subjective: TVT-O (85 %); TVT (100 %)
		TVT		Subjective cure (absence of SUI symptoms)		Objective: TVT-O (85 %); TVT (91 %)
Porena et al. [13]	50	TOT (Obtape)	VLPP≤60 cm H_20	Objective cure (stress test) Subjective cure (absence of SUI symptoms)	31 (±15); 31 (±12)	Subjective: TOT (68 %); TVT (76 %)
		TVT		IIQ-7, UDI-6		Objective: TOT (68 %); TVT (76 %)
Rechberger et al. [12]	85	TOT (IVS-4)	VLPP≤60 cm H_20	Objective cure (stress test)	18	Subjective: TOT (62.5 %); TVT (68.9 %)
		TVT (IVS-2)		Subjective cure (absence of SUI symptoms)		Objective: TOT (63 %); TVT (69 %)
Schierlitz et al. [9]	147	TOT (Monarc) TVT	VLPP≤60 cm H_20	Objective cure (stress test) Subjective cure (absence of SUI symptoms, repeat surgery)	36	Subjective: TOT (80 %); TVT (98.6 %)
		TVT	MUCP≤20 cm H_20	IIQ-7, UDI-6		Objective: TOT (68 %); TVT (79 %)
Tanuri et al. [18]	12	TOT (Safyre)	VLPP≤60 cm H_20	Objective cure (stress test) Subjective cure (absence of SUI symptoms)	12	Subjective: TOT (75 %); TVT (100 %)
		TVT (Safyre)		Kings Health Questionnaire (KHQ)		Objective: N/A

MUS mid-urethral slings, *SUI* stress urinary incontinence, *ISD* intrinsic sphincter deficiency, *MUCP* maximum urethral closure pressure, *TVT* tension-free vaginal tape, *TOT* transobturator tape, *TVT-O* tension-free vaginal tape-obturator, *VLPP* Valsalva leak point pressure, *IIQ* Incontinence Impact Questionnaire, *UDI* Urogenital Distress Inventory

were examined (random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data, selective reporting and other possible sources of bias). Any disagreements regarding study selection, risk of bias assessment or data extraction were resolved by discussion. Relative risk for dichotomous outcomes with 95 % confidence intervals was calculated.

We used a fixed-effect approach to the analysis, unless there was evidence of heterogeneity across studies. Differences between trials were investigated when apparent from either visual inspection of the results or when statistically significant heterogeneity was demonstrated by using the Chi-squared test at the 10 % probability level or assessment of the I^2 statistic [6, 7].

Data analysis was performed using Review Manager, version 5.2 (Cochrane Collaboration, Oxford, UK). The Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system was used to assess and grade the quality of evidence for each individual outcome [8].

Results

The flow of the literature review through the assessment process is illustrated in the PRISMA diagram (Fig. 1). We screened the 841 records identified by the literature searches. 776 of these records were excluded based on the title, abstract or full text review. Altogether, 65 reports of 12 studies were randomised trials that met the criteria for inclusion. Only 8 of these had contributable data for meta-analysis. The authors were contacted where data were deemed to have been collected but reported in a manner that negated extraction. Of the 8 trials contributing data to the meta-analysis, all carried out urodynamic assessment, 2 trials indicated that women with mixed urinary incontinence were included and only 1 trial [9] carried out concomitant surgery in some women. Exclusion criteria were non-randomised trials, trials that did not include a mid-urethral sling operation or trials where the women included were not urinary incontinent in association with ISD. Twelve trials compared retropubic MUS versus transobturator MUS [9–20]. Characteristics of the studies included are summarised in Table 1.

Risk of bias

The risk of bias in the trials included was variable, with only few trials judged to be at a high risk of bias in certain domains, but a relevant proportion were judged to be unclear. We were unable to assess publication bias using the funnel plot method owing to the limited number of studies. In over 50 % of studies random sequence generation was judged to be adequate, for example, with the use of a computer-generated list or a table of random numbers. Approximately 25 % of trials confirmed that secure concealment of the randomisation process was used, for example, allocation by a remote person or the use of sealed envelopes. Blinding of participants and personnel was unclear in the majority of trials. This is an obvious limitation with trials comparing surgical interventions where different skin incisions are made. Blinding of the postoperative reviewer was adequately reported in only 30 % of trials. Loss to follow-up in most trials was minimal, and in approximately 60 % of the trials included the risk of attrition bias was judged to be low. Our judgement about each risk of bias outcome for each study is presented in risk of bias summary (Fig. 2) and presented as percentages across all included studies is represented in the risk of bias graph (Fig. 3).

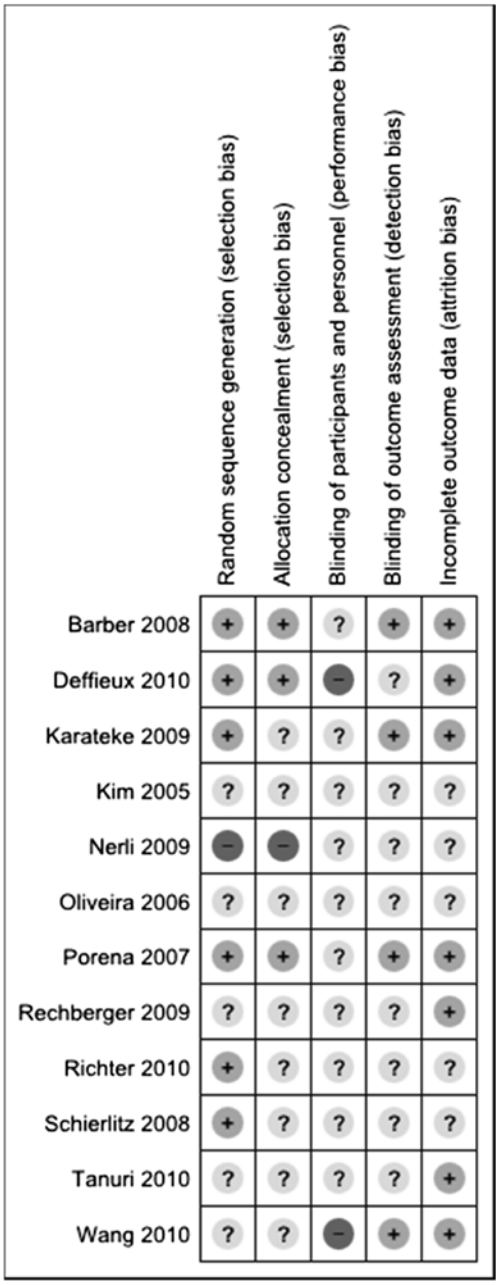

Fig. 2 Risk of bias summary: review authors' judgements about each risk of bias item presented for each study included

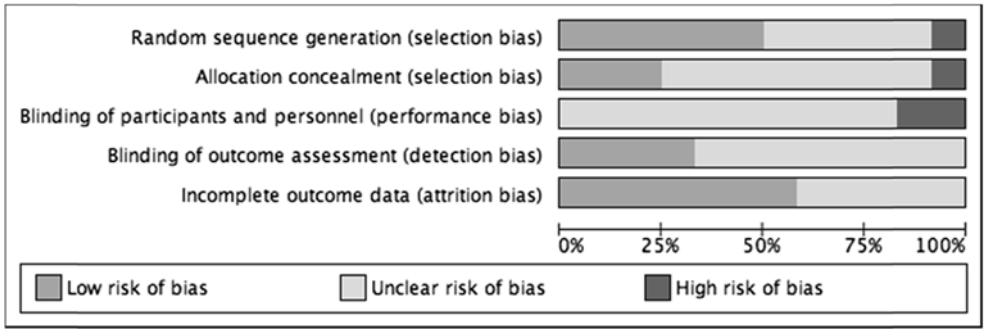

Fig. 3 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all the studies included

Effects of interventions

Eight trials with data contributed by 399 women show a statistically significant difference in short and medium term (≤5 years) subjective cure rates. The number of women reporting cure in the transobturator group was 150/199 and the retropubic group at 171/200. This gives a 12 % relative risk reduction in achieving cure with the TOR route (RR 0.88, 95 % CI 0.80 to 0.96, I^2=0 %, low quality evidence by GRADE); Fig. 4; Table 2). The subjective cure rates ranged from 60 % to 100 % with a median of 77.5 % in the TOR group, and from 50 % to 100 % with a median of 82.5 % in the RPR group.

In the five trials reporting objective cure rates there was no statistically significant difference between the two groups, with rates of 110 out of 159 in the transobturator group and 126 out of 165 in the retropubic group (RR 0.90, 95 % CI 0.79 to 1.03, I^2=0 %, 324 women, moderate quality evidence; Fig. 5).

Adverse events

Only one trial [9] reported outcome data on adverse events. No significant difference was found between the treatment groups with regard to post-operative voiding dysfunction or de novo urgency or urgency urinary incontinence (RR 0.43, 95 % CI 0.14 to 1.35 and RR 0.66, 95 % CI 0.34 to 1.13 respectively). The same trial showed that the risk of needing to undergo repeat incontinence surgery in the long term (≥5 years) was higher with the TOR (RR 14.4, 95 % CI 1.95 to 106, 147 women).

Quality of life

Pre- and post-operative quality of life (QoL) scores were quantitatively assessed in two trials [9, 16] using the Incontinence Impact Questionnaire (IIQ-7). This demonstrated improved QoL post-operatively with no significant difference between the treatment groups (mean difference −0.70, 95 % CI −2.10 to 0.70; Fig. 6). UDI-6 scores in the same trials also showed an overall marked improvement from baseline in post-operative scores, irrespective of the route used.

Economic measures

None of the trials included in this analysis performed economic analysis.

Discussion

This systematic review and meta-analysis of randomised controlled trials in women with ISD-associated SUI showed higher efficacy of treatment with a retropubic approach to MUS insertion up to 3 years following treatment. Patient reported subjective cure was 75.4 % in the TOR group and 85.5 % in the retropubic group. In terms

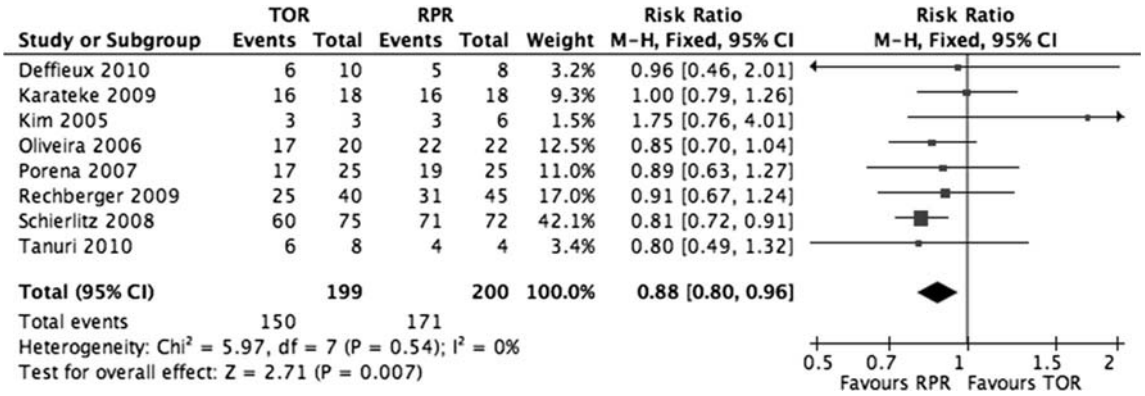

Fig. 4 Subjective cure: short and medium term (up to 5 years). *M–H* Mantel–Haenszel method, *RPR* retropubic route, *TOR* transobturator route

Table 2 Summary of findings: Grading of Recommendations, Assessment, Development and Evaluations (GRADE). Transobturator mid-urethral sling compared with retropubic mid-urethral sling for intrinsic sphincter deficiency-associated stress urinary incontinence in women.

Patient population: women with stress urinary incontinence associated with intrinsic sphincter deficiency; setting: hospital; intervention: transobturator (TOR) MUS; comparison: retropubic (RPR) MUS

Outcomes	Anticipated absolute effects[a] (95 % CI)		Relative effect (95 % CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with RPR MUS	Risk with TOR MUS				
Subjective cure (short-medium term) follow-up: up to 5 years	780 per 1,000	686 per 1,000 (624 to 749)	RR 0.88 (0.80 to 0.96)	399 (8 RCTs)	⊕⊕◯◯ low [1]	Median rate across both groups used as the assumed control rate in the RPR group
Objective cure (short-medium term); follow-up: up to 5 years	724 per 1,000	652 per 1,000 (572 to 746)	RR 0.90 (0.79 to 1.03)	324 (5 RCTs)	⊕⊕◯◯ low [2]	Median rate across both groups used as the assumed control rate in the RPR group
Quality of life assessed using the Incontinence Impact Questionnaire (IIQ-7); follow-up: 12–14 months	The mean quality of life in the control group was 0	The mean quality of life in the intervention group was 0.7 lower (2.1 lower to 0.7 higher)	–	183 (2 RCTs)	⊕⊕⊕◯ moderate [3]	
Voiding dysfunction (short term); follow up: 12 months	Study population 113 per 1,000	48 per 1,000 (16 to 152)	RR 0.43 (0.14 to 1.35)	162 (1 RCT)	⊕⊕◯◯ low [4]	
De novo urgency/ urgency urinary incontinence, follow up: 12 months	Study population 348 per 1,000	230 per 1,000 (132 to 394)	RR 0.66 (0.38 to 1.13)	136 (1 RCT)	⊕⊕◯◯ low [4]	
Repeat incontinence surgery (long term); follow up: 5 years	Study population 14 per 1,000	200 per 1,000 (27 to 1,000)	RR 14.40 (1.95 to 106.22)	147 (1 RCT)	⊕◯◯◯ very low [4, 5]	

High quality: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: we are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect

Very low quality: we have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect

1. Sequence generation unclear in 4 out of 8 trials and allocation concealment unclear in 6 out of 8 trials, so we downgraded the quality rating by two levels

2. Sequence generation unclear in 3 out of 5 trials and allocation concealment unclear in 4 out of 5 trials, so we downgraded the quality rating by two levels

3. Downgraded by one level because the risk of bias judged as unclear

4. As there was only one study with very few events and CIs around estimates of effect included appreciable benefit and appreciable harm, we downgraded by two levels

5. The wide confidence interval was judged to include a threshold for appreciable harm considered to be >25 % increase in RR; thus, we downgraded by one level

[a] The risk in the intervention group (and its 95 % confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95 % CI)

of relative risk, this is a 12 % higher rate of cure in women undergoing an RPR procedure. This could be as little as 4 % higher or as much as 20 % higher in comparison to a TOR approach. Objective cure that was assessed at urodynamics with a negative cough stress test was not significantly different in the two groups. Quality of life was improved with the employment of an MUS procedure, irrespective of the route of insertion. Postoperative voiding dysfunction, de novo urgency and urgency urinary incontinence, and the need for repeat incontinence surgery in the medium term were assessed only by one randomised controlled trial [9]. This showed no significant difference in the previously mentioned outcomes. At 5 years this same trial showed that there was a significantly higher chance of needing a repeat incontinence procedure following the TOR procedure.

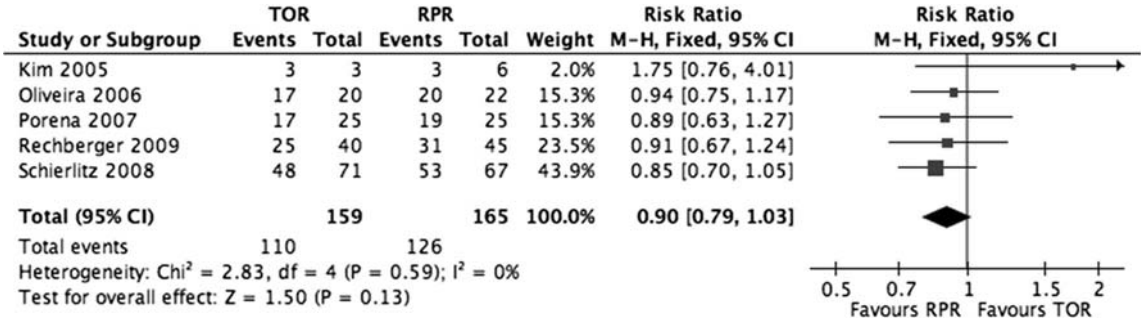

Fig. 5 Objective cure: short and medium term (up to 5 years)

Women with ISD-associated SUI represent a subset of patients where SUI presents in a severe form and treatment success is poor. In the past, pubovaginal slings were used for treating this cohort of women, but limited success and high rates of complications have limited their use in current practice. Consequently, MUS and urethral bulking agents have become increasingly popular. There is a plethora of randomised controlled trial data demonstrating the effectiveness of MUS procedures in a non-select group of women with SUI. This evidence confirms the equivalent success of RPR and TOR tapes, but with higher morbidity incurred with the use of RPR [21]. The question for clinicians is whether the use of a transobturator tape, in view of its lower morbidity, compromises treatment success in this selected cohort of women with severe symptoms from ISD. Currently, evidence to inform this choice between RPR and TOR is lacking. Any existing evidence from randomised trials in this group is limited by the small sample size, which is inadequately powered to provide evidence of effectiveness of primary outcomes.

To our knowledge this is the first systematic review and meta-analysis of RCTs addressing this clinically important question. Although the results of the study are weighted by one large trial, the outcome results seem in keeping with the limited published observational and retrospective study data. These studies consistently show that irrespective of the route of MUS insertion the success rates in women with ISD are globally lower than those women without ISD, but furthermore the success rates appear lower again with the employment of a transobturator route over the retropubic route [22–28]. A possible explanation for the lower success rate in TOR procedures may be the less perpendicular axis of the transobturator tape to the urethral axis, leading to less circumferential compression of the urethra. Thus, in the TOR the tape lies in a transverse horizontal position, unlike the U-shaped support in the retropubic tape. The narrower mean angle underneath the urethra of the retropubic tape at rest provides more circumferential compression of the urethra and increased urethral pressure during exertion. Similarly, ultrasound studies have shown the transobturator tapes both at rest and during the Valsalva manoeuvre to have a more distal position on the urethra and also with less kinking of the urethra during straining than its retropubic counterpart [29].

The results of this study raise some questions regarding implications for current practice. It highlights that there is a need to appropriately diagnose women with ISD-associated SUI, so as to avoid the risk of failure and need for a repeat procedure if these women were to undergo a transobturator procedure. We know that women experiencing failed procedures endure the distress and psychological sequelae associated with failure, as well as ongoing, potentially worsening symptoms. This potentiates the need to choose the correct treatment modality at the earliest opportunity, suggesting that despite the controversies that exist surrounding the diagnosis of ISD, this should be routinely screened for at urodynamic testing.

This review is limited by a number of factors. Unfortunately, the diagnosis of ISD is far from being universally accepted, whereas urethral hypermobility is recognised as a significant contributory factor to SUI. In fact, the presence of urethral hypermobility increases the chance of sling success, and its absence increases the risk of sling failure. The relevance of this has been highlighted by Haliloglu et al. who found that in a cohort of 65 women with SUI treated with TOT, women with ISD in the presence of a fixed urethra (no urethral hypermobility) had the poorest outcome at the 2-year follow-up. In this group cure rates were 66.7 %, whereas in women who had ISD in conjunction with a hypermobile urethra cure rates were 87.5 % [30].

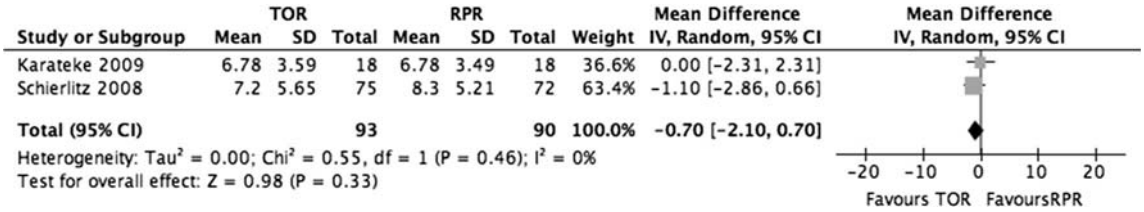

Fig. 6 Quality of life assessment: short and medium term (up to 5 years)

There are very few RCTs addressing the specific question of intrinsic sphincter deficiency in SUI; thus, the number of studies included is relatively small. Many of the trials provided data from a subgroup analysis. Of the trials that reported ISD very few reported urethral hypermobility specific to that cohort of women. Hypothetically, if a disproportionate number of women had urethral hypermobility in one group then the success rate is likely to be skewed. However, adequate randomisation should give each group an equal chance of including women with urethral hypermobility. In this systematic review randomisation was judged to be adequate in only 50 % of the trials included, including the largest trial contributing the most data.

The RCTs included have very small sample sizes, with the exception of one study, which invariably contributes a significant weight to the meta-analysis. There are also inherent limitations accruing from methodological problems in the primary studies. Risk of bias in most domains was judged to be unclear, and many of the primary studies did not report outcomes of relevance specific to this subgroup of women.

A final limitation in the focus of our review was to compare the use of MUS in the management of women with ISD-associated SUI. A review of other treatment modalities used in this group, e.g. urethral bulking agents, would further inform treatment choice.

This is the first systematic review and meta-analysis of RCTs addressing the use of MUS in ISD urinary incontinent women and it shows that subjective cure is approximately 10 % higher with a retropubic approach to MUS insertion as opposed to the transobturator approach. With this finding comes an implication for clinical practice to ensure that clinicians are correctly diagnosing and treating this cohort of women. The limitations identified should be taken into consideration when interpreting the result of this meta-analysis. Further evidence from future randomised controlled trials specifically addressing the problem of intrinsic sphincter deficiency-associated stress urinary incontinence will provide more robust evidence and broaden our knowledge on how best to manage these women.

Conflicts of interest A.A. Ford: partial sponsorship by Johnson & Johnson to the International Urogynaecology Association meeting, Washington, 2014; J.A. Ogah: full sponsorship by Astellas UK to the International Urogynaecology Association meeting, Nice, 2015.

Funding None to declare.

Appendix 1

Cochrane incontinence group specialised register

The terms used to search the Incontinence Group Specialised Register, 26 June 2014, are given below:

(TOPIC.URINE.INCON*)
AND
({DESIGN.CCT*} OR {DESIGN.RCT*})
AND
{INTVENT.SURG.SLIN*} OR {INTVENT.SURG.SUBURETHRAL SLING.} OR {INTVENT.SURG.ABDO.SLING.}

(All searches were of the keyword field of Reference Manager 2012.)

Embase and Embase Classic (on OVID SP) was searched from 1947 to week 25 20014 on 26 June 2014 and was limited to those years not fully covered by the Embase search for CENTRAL carried out by the Cochrane Collaboration. Limited to: (2010* to 2014*).em. The following search strategy was used:

1. Randomized Controlled Trial/
2. crossover procedure/ or double blind procedure/ or parallel design/ or single blind procedure/
3. Placebo/
4. placebo$.tw,ot.
5. random$.tw,ot.
6. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw,ot.
7. crossover.tw,ot.
8. cross over$.tw,ot.
9. allocat$.tw,ot.
10. trial.ti.
11. parallel design/
12. triple blind procedure/
13. or/1-12
14. exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/
15. exp human/ or exp "human tissue, cells or cell components"/
16. 14 and 15
17. 14 not 16
18. 13 not 17
19. incontinence/ or mixed incontinence/ or stress incontinence/ or urge incontinence/ or urine incontinence/
20. continence/
21. overactive bladder/
22. micturition disorder/ or lower urinary tract symptom/ or pollakisuria/
23. urinary dysfunction/ or bladder instability/ or detrusor dyssynergia/ or neurogenic bladder/ or urinary urgency/ or urine extravasation/
24. (incontinen$ or continen$).tw.
25. ((bladder or detrusor or vesic$) adj5 (instab$ or stab$ or unstab* or irritab$ or hyperreflexi$ or dys?ynerg$ or dyskinesi$ or irritat$)).tw.
26. (urin$ adj2 leak$).tw.

27. ((bladder or detrusor or vesic$) adj2 (hyper$ or overactiv$)).tw.
28. (bladder$ adj2 (neuropath$ or neurogen* or neurolog$)).tw.
29. (nervous adjpollakisur$).tw.
30. or/19-29
31. (tape* or sling*).tw.
32. 18 and 30 and 31
33. (2010* or 2011* or 2012* or 2013* or 2014*).em.
34. 32 and 33

WHO ICTRP (on http://www.who.int/ictrp/en/) was searched on 30 June 2014 using the following search string: Continent OR continence OR incontinent OR incontinence AND tape* OR sling* AND random*

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